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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,775	10/10/2003	Jeffrey T. McGrew	2902-B	1327

22932 7590 12/20/2005

IMMUNEX CORPORATION
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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/683,775	MCGREW, JEFFREY T.	
	Examiner	Art Unit	
	Agnes B. Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52,56-58,62-65,68-71 and 74* is/are rejected.

7)☒ Claim(s) *53-55, 59-61, 66, 67, 72, 73* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/10/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The restriction requirement sent in the paper dated August 9, 2005 is vacated regarding Groups I and II. Thus, examiner rejoined Groups I and II. However, the restriction in Group I that refers to additional groups with patently distinct inventions is maintained, where the Applicant elected an immunoglobulin.

Claims 50-74 are pending.

Claims 50- 74 with respect to immunoglobulin molecule are currently examined.

The non-final rejection office action sent on September 22, 2004 has been vacated, because previous examiner considered claims 1-49 that were cancelled. Therefore, a restriction requirement was sent on August 9, 2005 to prosecute pending claims 50-74.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP, paragraph 821.01. The restriction requirement is still deem proper and is therefore made final.

This application is continuation of 09/687,050, filed on 10/12/2000, now patent U.S. 6,632,637, which claims benefit of 60/159,177, filed on 10/13/1999.

The Terminal Disclaimer submitted on March 21, 2005, obviates a provisional double patenting rejection over a prior patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 50-52, 56-58, 62-65, 68-71, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levinson et al. in view Clump et al.

Levinson et al. teach a polycistronic construction of xenogeneic sequences expressible in eukaryotic cell; where DHFR encoding sequences are under control of the same promoter with another foreign gene that can be amplified with methotrexate, and thus cause coamplification of the foreign gene. See Figure 1, for example; and column 1, lines 58-64. Further, to express the desired product, the host cells used in the invention were vertebrate cells grown in tissue culture. See for example, column 8, lines 47-53.

Levinson et al. does not teach expression of an immunoglobulin in a polycistronic construct.

Klump et al. teach recombinant vectors that may direct the expression of more than one heterologous sequence; where such multiple sequences may be controlled either by a single promoter (whether it is present in the vector on in the genome into which the vector is integrated), or preferably, by one or more additional promoters and may also include internal ribosome binding sites ("IRBS") in the event polycistronic message are employed. Column 15, lines 64-67, and column 16, lines 1-4. Further, the

upstream untraslated region of the immunoglobulin heavy chain binding protein has been shown to support the internal engagement of a bicystronic message; and where the sequence may be readily incorporated into a vector in order to express multiple genes from a multicistronic message whose cistrons begin with the sequence. See column 16, lines 5-11.

Therefore, it would have been obvious to one of an ordinary skill in the art to design a polycistronic construct with a polyadenylation site, DHFR and IRBS that expresses immunoglobulin because the polycistronic constructs are known and commonly used as per Levinson et al., and expression of immunoglobulins in such constructs as taught by Klump et al. is also known. Further, the method for obtaining a recombinant protein by culturing a cell line would be obvious, as such method is known and commonly used in the prior art.

Objections to Claims

Claims 53-55, 59-61, 66, 67, 72, and 73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

SEQ ID NOs:1, 3, and residues 80 through 222 of SEQ ID NO:1 are novel because they are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. or call 866-217-9197.

AR

ROBERT A. WAX
PRIMARY EXAMINER